CLAIMS

What is claimed is:

1. A composition comprising at least one insoluble active substance together with at least one wetting agent, wherein the concentration of said wetting agent is sufficient to form a stable, flocculated suspension of said active substance.

2. The composition of claim 1, wherein said wetting agent is within the range of about 0.01% to about 0.04% w/w.

3. The composition of claim 1, wherein the concentration of said wetting agent is about 0.02% w/w.

4. The composition of claim 1, wherein said active substance is megestrol acetate and said wetting agent is docusate sodium.

5. The composition of claim 1, wherein the concentration of said active substance is within the range of about 0.1% to about 25% w/v.

6. The composition of claim 1, wherein the concentration of said active substance is within the range of about 1 to about 5% w/v.

7. The composition of claim 1, wherein the concentration of said active substance is about 4% w/v.

8. The composition of claim 1, further comprising at least one water-soluble polymer.

9. The composition of claim 8, wherein said polymer is present at a concentration of greater than about 5% w/w.

10. The composition of claim 8, wherein said polymer is present at a concentration of within the range of about 10% to about 30% w/w.

11. The composition of claim 8, wherein said polymer is present at a concentration of about 20% w/w.

12. The composition of claim 8, wherein said polymer is polyethylene glycol.

13. The composition of claim 1, further comprising at least one hydrocolloid.

14. The composition of claim 13, wherein said hydrocolloid is at least one material selected from the group consisting of pharmaceutically acceptable gums.

15. A method for forming an aqueous flocculated suspension containing an insoluble micronized active substance together with a wetting agent to form a stable, resuspendable flocculated suspension of said active substance, which comprises adding said wetting agent in an amount below which the floccule size of said active substance in said suspension starts to increase.

16. The method of claim 15, wherein said active substance is megestrol acetate.

17. The method of claim 15, wherein said wetting agent is docusate sodium.

18. The method of claim 17, which comprises adding said docusate sodium in an amount of about 0.01 to about 0.04% w/w.

19. The method of claim 17, which comprises adding said docusate sodium in an amount of about 0.02% w/w.

20. The method of claim 15, wherein said flocculated suspension comprises floccules having a mean floc size diameter of at least about 12 microns.

21. The method of claim 15, wherein said flocculated suspension comprises floccules having a mean floc size diameter of about 12 to about 50 microns.

22. The method of claim 15, wherein said flocculated suspension comprises floccules having a mean floc size diameter of about 23 to about 28 microns.

23. An oral pharmaceutical composition, comprising:

a) about 0.5 to about 10% w/v of megestrol acetate;

b) about 0.01 to about 0.04% w/w of docusate sodium; and

c) about 10 to about 30% w/w of at least one suspending agent.

24. The composition of claim 23, comprising about 0.01 to about 0.025% w/w of docusate sodium.

25. The composition of claim 23, wherein said suspending agent is polyethylene glycol.

26. The composition of claim 24, comprising about 0.01 to about 0.02% w/w of docusate sodium.

27. The composition of claim 23, wherein said second suspending agent is xanthan gum.

28. The composition of claim 27, wherein said second suspending agent is present in said composition in an amount of from about 0.1 to about 0.3% w/w.

29. The composition of claim 23, wherein said composition contains floccules having a mean floc size diameter of at least about 12 microns.

30. The composition of claim 23, wherein said composition contains floccules having a mean floc size diameter of at least about 21 microns.

31. An oral composition, comprising about 1 to about 8% w/v of megestrol acetate, a first suspending agent consisting essentially of about 15 to about 25% w/w of polyethylene glycol; a wetting agent consisting essentially of 0.01 to about 0.04% of docusate sodium w/w; and further comprising from about 0.1 to about 0.3% w/w of xanthan gum.

32. The composition of claim 31, wherein said composition is in the form of an aqueous flocculated suspension which is storage stable for at least about 3 months.

33. The composition of claim 31, wherein said composition is storage stable for at least about 12 months.

34. A method of forming an oral pharmaceutical composition, comprising:

combining a first portion of polyethylene glycol with xanthan gum and water in a first vessel;

combining a second portion of polyethylene glycol, docusate sodium and megestrol acetate in a second vessel;

combining the contents of said first vessel with the contents of said second vessel.

35. A method of forming an oral pharmaceutical composition, comprising:

combining a first portion of polyethylene glycol, a first portion of water , docusate sodium and megestrol acetate in a first vessel;

combining xanthan gum, a second portion of water and a second portion of polyethylene glycol in a second vessel; and

combining the contents of said first vessel with the contents of said second vessel.

36. An oral pharmaceutical composition in the form of a stable flocculated suspension in water capable of being redispersed after being allowed to settle at a temperature of 40°C and 75% relative humidity for a period of three months, comprising:

(a) about 10 to about 200 mg per mL micronized megestrol acetate;

(b) about 10 to about 40% by weight of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and

(c) about 0.0001 to about 0.03% by weight of a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present in said composition.

37. The composition of claim 36, wherein the surfactant is anionic.

38. The composition of claim 37, wherein the surfactant is docusate sodium.

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39. The composition of claim 1, wherein said wetting agent is within the range of about 0.001 to about 0.05% w/w.